K043598

DEC 16 2005

510(k) Summary

(As required by 21 CFR 807.92(c))

SUBMITTER BY

BIONET CO., LTD.
401 Kikox Venture Tower
188-5 Guro-Dong, Guro-Gu
Seoul, REPUBLIC OF KOREA
(PHONE) 82-2-6300-6410
(FAX) 82-2-6300-6425

CONTACT PERSON

(NAME) Hyun-Joo Kwon
(TITLE) Regulatory Affairs Engineer
(PHONE) 82-2-6300-6433
(FAX) 82-2-6300-6425

US AGENT

(NAME) Mr. Steven Minn
(ADDRESS) BIONET AMERICA, INC.
3345 Wilshire Blvd., Suite 811
Los Angeles, CA 90010
(PHONE) 888-292-6060
(FAX) 213-389-0036

DATE OF SUMMARY

December 24, 2004

DEVICE NAME

(Proprietary Name) FC-1400
(Common Name) FC-1400
(Classification Name) Perinatal monitoring system and accessories
(Regulation Number) 21 CFR §884.2740
(Regulatory Class) II
(Product Code) HGM

PREDICATE DEVICES

510(k) Number: K002503
Device Name: FETALGARD Lite
Submitter by: Analogic Corporation

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DEVICE DESCRIPTION

FC-1400 is a fetal monitor, providing continuous monitoring, displaying, printing and recording of twin Fetal Heart Rate (FHR), Fetal Movement (FM) and Uterine Activity (UA) for antepartum testing and monitoring.
FC-1400 irradiates the ultrasound wave to maternal abdomen, and detects the Doppler effect signal reflected from the heart of the fetus.
FC-1400 extracts FHR and FM from this signal and provides the fetal heart beat sound with internal speaker.
FC-1400 measures the UA of a pregnant woman using TOCO sensor.
FC-1400 displays FHR, UA and FM with waveforms and numbers on the color LCD screen, saves them in internal flash memory and prints a part of them with high speed to review in details.
It provides the most accurate and continuous obstetrical measurements enduring and rigorous hospital environment.

INTENDED USE

FC-1400 detects and displays twin Fetal Heart Rate (FHR), Fetal Movement (FM) and Uterine Activity (UA) in a real time on the color LCD viewer, and also provides the fetal heart beat sound with internal speaker. Twelve hours of tracing may be stored and later retrieved for printing. It intended to be used by trained healthcare personnel. It is not intended for home use.

COMPARISION OF TECHNOLOGICAL CHARACTERISTICS

Comparison Areas	FC-1400	Predicate Device
Indications for use	This detects and displays twin Fetal Heart Rate (FHR), Fetal Movement (FM) and Uterine Activity (UA) in a real time on the color LCD viewer, and also provides the fetal heart beat sound with internal speaker. Through the color LCD viewer user can trace a stored data for 12 hours easily and print a part of them with high speed to review in details. It provides the most accurate and continuous obstetrical measurements enduring noisy and rigorous hospital environment.	Similar
Where used	It intended to be used by trained healthcare personnel. It is not intended for home use.	Identical
Performance	Fetal Heart Rate (FHR) for single or twin Uterine Contraction (UC) Printing Monitoring Results Interface through RS232	Similar
Standard met	-Electrical safety: IEC60601-1 -EMC: IEC60601-1-2) so on. -Biocompatibility: ISO10993	Similar

NONCLINICAL TESTS

It has tested for electrical safety according to IEC60601-1, electromagnetic compatibility according to IEC60601-1-2, and biocompatibility in accordance with the guidelines of International Organization for Standardization: Biological Evaluation of Medical Devices.

CONCLUSION

FC-1400 is substantial equivalent to predicated device FETALGARD Lite(K002503) of Analogic Corporation and Philips Avalon CTS Cordless Fetal Transducer System(K023931) of Philips.

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NONCLINICAL TESTS	It has tested for electrical safety according to IEC60601-1, electromagnetic compatibility according to IEC60601-1-2, and biocompatibility in accordance with the guidelines of International Organization for Standardization: Biological Evaluation of Medical Devices.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

BioNet/BioNet America, Inc.
% Mr. Sun-Young Jeong
Regulatory Affairs Engineer
Research Institute for Medical Instruments
Medical Industry Techno Tower
R205, 1272 Maeji Heungup
Wonju, Kwangwon-Do
Republic of Korea

Re: K043598
Trade/Device Name: FC-1400 Perinatal Monitor
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: November 22, 2005
Received: November 22, 2005

Dear Mr. Jeong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

APPLICANT BIONET CO., LTD.

510(k) NUMBER K043598

DEVICE NAME FC-1400

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon

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